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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,486	02/05/2002	Mariana Nacht	GA0217C	8923
7590 10/08/2004				
Elizabeth Lassen Genzyme Corporation 15 Pleasant Street Connector Framingham, MA 01701-9322			EXAMINER HUFF, SHEELA JITENDRA	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/068,486	<b>Applicant(s)</b> NACHT, MARIANA	
	<b>Examiner</b> Sheela J Huff	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Response to Amendment

The amendment filed on 9/13/04 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-6 are pending.

The rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments.

The rejection under 35 U.S.C. 112, first paragraph, (written description is withdrawn in view of applicant's amendment.

The rejection under 35 U.S.C. 112, first paragraph, (enablement) is withdrawn in favor of a new one.

### ***Priority***

Applicant argues that the instant set of claims has priority to the provisional application and cites pages 10-11 and 13-14 of the provisional application. The instant set of claims is directed to methods of modulating or reducing angiogenesis and/or endothelial cell proliferation by administering Claudin-7 and the reduction of tumor growth by administering Claudin-7. The provisional application merely suggests that the expression pattern of Claudin-7 may "play a role in promoting or maintaining tumorigenesis". A mere suggestion in the provisional application that suggests involvement in tumorigenesis does not translate to **using** the Claudin-7 to modulate or reduce angiogenesis and/or endothelial cell proliferation and to reduce tumor growth.

Thus, the priority to the provisional application is denied.

***Claim Rejections - 35 USC § 112***

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In Re Colianni*, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in *Ex Parte Forman*, 230 USPQ 546 (BPAI 1986). Among these factors are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the breath of the claims,
5. the amount of direction or guidance present, and
6. the presence or absence of working examples.

The following is an analysis of these factors in relationship to this application.

Nature of the invention

Applicant discloses and claims the modulation or reduction of angiogenesis and/or endothelial cell proliferation by administering Claudin-7 and the reduction of tumor growth by administering Claudin-7.

State of the Art

The state of the art does not show that claudin -7 can be used either in vitro or in vivo to modulate angiogenesis and/or endothelial cell proliferation or to reduce tumor growth.

Guidance/ Working Examples/Predictability

The specification is prophetic in nature. Even though the specification does provide a prophetic in vitro assay which may be used to validate angiogenic activity or tumorigenic activity, the specification provides no objective examples of these assays actually identifying claudin -7 as possessing the above activities. And even if these prophetic assays did show that claudin-7 had the aforementioned activities, there is no assurance that the claudin-7 would be active in vivo. The claims are directed to in vivo treatments and such treatments, in and of themselves, are unpredictable because pharmacokinetic factors such as the stability of the peptides in the body, half-life, absorption efficiency, binding affinity for target cells, biotransformation, and the rate of clearance from the body are important consideration for the efficacy of the claimed subject matter and yet have not been considered. In the absence of these considerations, there is no assurance (ie. it is unpredictable) that the active claudin-7 would be available in effective doses at the target sites and for periods of time sufficient to effect the required cellular or biological responses.

Breadth of the claims

Applicant is not claiming broadly.

In view of the above, it is the Examiner's position that one skilled in the art could not make and/or use the invention without undue experimentation.

Response to Applicant's arguments

Applicant argues that the specification discloses the sequences (nucleic acid and protein) of claudin-7. The examiner is not saying that applicant does not have possession of claudin-7, the rejection is based on the lacking of showing how to use claudin-7.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

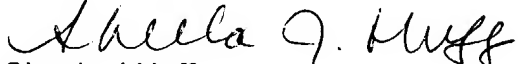
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh